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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,331	08/04/2003	Alan J. Polito	7035-0003.03	6774

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EXAMINER

HINES, JANA A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/634,331

Applicant(s)

POLITO ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/4/03.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 98-116 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 98-116 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 98-106 are drawn to an apparatus comprising a housing having a receptacle and an auto start means, classified in class 435, subclass 287.9.
 - II. Claims 107-111 are drawn to an apparatus comprising a housing; an auto start means and a test strip comprising an internal quality control means classified in class 435, subclass 287.3.
 - III. Claims 112-113 are drawn to a method of detecting an analyte in a sample by use of a lateral flow assay, classified in class 435, subclass 4.
 - IV. Claims 114-115 are drawn to a method of analyzing results of a lateral flow assay on a test strip, classified in class 435, subclass 39.
 - V. Claim 116 is drawn to a method of conducting quality control, classified in class 436, subclass 517.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the apparatus of group I comprises different components than the apparatus of group II. The apparatus of group II comprises a housing; an auto start means and a test strip comprising an internal quality control

means which the apparatus of group I does not. Therefore, in view of the different components and the different modes of operation the inventions are deemed distinct.

Searching the inventions of Group I or II together would impose a serious search burden. The inventions of Groups I or II have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the apparatuses of Groups I or II are not coextensive. The test strip comprising an internal quality control means is not required for the search of group I. The prior art teaches that apparatus can be made with the test strip and would not necessarily be applicable to using the apparatus of Group I. Moreover even if the apparatus of Group I were known, the apparatus of Group II may be novel and unobvious in view of the preamble and components of Group II.

Inventions I or II and III-V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, none of the methods require the use of the apparatus of group II or I. Devices that can determine the presence of a disease or condition are well known in the art and such devices typically provide qualitative results for the analyte being tested. Therefore, methods of detection and analysis can be conducted using well-known lateral flow analysis devices. Thus, the methods can be practiced with

materially different apparatus or by hand when using test strips with visually detectable labels.

Searching the inventions of Group I or II and III-V together would impose a serious search burden. The inventions of Groups I or II and III-V have a separate status in the art exemplified by their different classifications. Moreover, in the instant case, the search for the apparatus' and methods of the Groups are not coextensive. Furthermore, a search for one invention would not necessarily incorporate a search for another group if one group is novel or unobvious. Similarly, a search indicating that a group is known or would have been obvious would not extend to a holding that the other groups are known or would have been obvious. Thus inventions are distinct for the reasons given above.

Inventions III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions. The methods are distinct as claimed because they have different methods with different method steps; different functions and the effects have different final outcomes. Group III is drawn to a method of detecting an analyte in a sample by use of a lateral flow assay. The method of Group III has a different function, i.e., detecting an analyte, which is entirely different than a method for analyzing results of a lateral flow assay on a test strip or a method of conducting quality control, as recited in groups IV and V. The steps of group III are different than the steps

of group IV or V, since group III comprises providing a sample; allowing analyte to react with binding agent; measuring reflectance; deducing background reflectance; and determining amount of analyte presence. No other method recites the same steps. Similarly, the steps comprised in either groups IV or V is different than the remaining groups. The method of group III does not produce the same results as found in either group IV or V. Each group produces different effects and different functions when compared to the other groups. Moreover, the methodology and materials differ significantly. Therefore, for these reasons the inventions are patentably distinct.

Furthermore the distinct steps and products require separate and distinct searches. The inventions of Groups III-V have a separate status in the art as shown by their different classification. As such, it would be burdensome to search the inventions of groups III-V together.

3. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and have divergent subject matter, the search required for Group I is not required for Group II or III, restriction for examination purposes as indicated is proper.


4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 
November 13, 2004


NITA MINNIFIELD
PRIMARY EXAMINER
11-13-04